

Laporan praktek kerja profesi apoteker di corporate regulatory affairs PT. Kalbe Farma, Tbk. Jl. Jend. Ahmad Yani No. 2, Jakarta Timur, periode Februari - Maret 2016 = Report of profession internship in coorporate regulatory affair PT. Kalbe Farma, Tbk. Jl. Jend Ahmad Yani No. 2 East Jakarta on February - March 2016 / Grace Juli Carlina Nababan

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Abstrak

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Praktek Kerja Profesi Apoteker (PKPA) di PT. Kalbe Farma, Tbk bertujuan untuk mengetahui peranan, tugas, dan tanggung jawab apoteker di Industri Farmasi, khususnya di bagian Regulatory Affairs, mengetahui dan memahami mekanisme pendaftaran atau registrasi produk, baik obat dan produk biologi, suplemen makanan, pangan, kosmetika, serta alat kesehatan dan perbekalan kesehatan rumah tangga. Tugas khusus yang diberikan berjudul Perbandingan Regulasi Obat Flu dan Batuk di Wilayah ASEAN, Eropa dan di negara Amerika Serikat bertujuan untuk membandingkan regulasi obat flu dan batuk di wilayah ASEAN, Eropa dan di negara Negara Amerika Serikat

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ABSTRACT

Apotechary Profession Internship in PT. Kalbe Farma Tbk aims to determine the role, duties and responsibilities of pharmacists in the pharmaceutical industry, especially in the Regulatory Affairs, knowing and understanding the mechanism of products registration, both medicinal and biological products, food supplements, food, cosmetics, and medical devices and household health supplies. Special assignment given titled Comparison Flu and Cough Medicines Regulation in the ASEAN region, Europe and in the United States aimed to compare regulation of cough and cold medications in the ASEAN region, Europe and in the United States